K003828

MAY 1 8 2001

Section 7

Britt Corp
510 (k) Summary

Vaso Press DVT Foot Garment # VP 520

I. NAME OF SUBMITTER

Britt Corp
P.O. Box 547
Freehold\ld, NJ 07728
Phone: 732-817-1122

Contact Person: James Britton
Establishment Registration Number: 2249054

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name: Vaso Press DVT Foot Garment
Common or Usual Name: Compressible Limb Sleeve
Classification: Class II; JOW 870.5800

III. PREDICATE DEVICE

The Vaso Press DVT Foot Garment # VP 520 is substantially equivalent to devices in commercial distribution by the following company:
Healthcare Service and Supply's PVA/ALP Foot Sleeve, PO Box 1788, Tustin, CA 92681

IV. DESCRIPTION

The Vaso Press DVT Foot Garment consists of a brushed nylon outer material bonded to a foam inner liner. An inflatable polyvinylchloride (PVC) pressure bag is encapsulated between an additional nylon/foam material. An exit tube leads out from the pressure bag for connection to the Vaso Press Pump. The patient contact material is polyurethane foam. The Vaso Press DVT Foot Garment is provided non-sterile.

V. INTENDED USE

The Vaso Press DVT Foot Garment is recommended for use in patients for whom external compression therapy is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

VI. TECHNOLOGICAL CHARACTERISTICS

The Vaso Press DVT Foot Garment has the same technological characteristics as the predicate device. The material used in the foot garment is similar and the operation of the pump and garments also are similar.

Testing performed by Britt Corp has shown that the garments are equivalent in performance as the Healthcare Service and Supply PVA/ALP Foot Sleeve.

VII. BIO-COMPATIBILITY ASSESSMENT

To assess the Biocompatibility the following tests were conducted

1. PRIMARY SKIN IRRITATION TEST-ISO

Results: The test article is considered a negligible irritant under the experimental conditions employed.

2. L929 MEM ELUTION TEST-ISO

Results: The test article, Polyfoam Knit, is considered non-cytotoxic and meets the requirements of the Elution Test, ISO 10993

3. KLIGMAN MAXIMIZATION TEST Sodium Chloride (MODIFIED)-ISO Results: ... (0% sensitization)...a Grade I reaction and the test article is classified as having weak allergenic potential. A grade I sensitization is not considered significant according to Magnusson and Kligman (1969, 1970)

4. KLIGMAN MAXIMIZATION TEST Cottonseed Oil (MODIFIED)-ISOResults: (0% sensitization).... this is a Grade I reaction and the test article is classified as having weak allergenic potential. A Grade I sensitization rate is not considered significant according to Magnusson and Kligman (1969, 1970).

VII. <u>PERFORMANCE TESTING</u>

PRODUCTS TESTED

1. The Vaso Press DVT Foot Garment with the Vaso Press DVT Pump
2. The Healthcare Service and Supply PVA/ALP Foot Sleeve and the ALP Pump. Currie Medical Specialties, Inc., Monrovia, CA, distributes

this product. Reference is made in the documentation included in this section to "Currie" which is the Healthcare Service and Supply product.

TESTING CONDUCTED

Test #1 Demonstration of the similarity between the pressures derived between the VP 520 Foot Garment and the Healthcare Service and supply PVA/ALP Foot Sleeve.

Method- A mercury manometer that is in line via a "Y" connector to measure the delivered pressure to the foot devices. A stopwatch was used to time the pressure to 20 mmHg, 40-mmHg and 60 mmHg (low, middle and high settings). Readings were taken for the time to reach the pressure settings, total pressurization duration and deflation pressure time. Ten readings were taken and recorded for each out put port.

Test #2- Static burst pressure testing on the Vaso Press Foot Garment at twice the maximum recommended applied pressure and twice the maximum duration.

Method A Vaso Press Pump was used to inflate the foot garment to 120-mmHg pressure for six days.

PURPOSE- Testing to demonstrate safety and efficacy of the device for the intended use.

DISCUSSION

Test # 1 A complete cycle for inflation and deflation of each port is 60 seconds. The Vaso Press Pump was used to inflate the Vaso Press Foot Garment and the ALP Pump to inflate the PVA/ALP Foot Sleeve. The garments were wrapped around a 5-inch diameter PVC tube to simulate a foot. The pumps then inflated the garments. A stopwatch was used to record the time to 20 mmHg, 40 mmHg and 60 mmHg and then the time at which the pressure was released. Both pumps have a specification to inflate to the selected pressure within 4 seconds and release at 12 seconds into the cycle. The second port starts to inflate 30 seconds into the cycle with the same time requirement (4-seconds to 40-mmHg pressure) and release at 42 seconds.

The Vaso Press DVT VP 520 garment inflated in 2.09 seconds to 40 mmHg, and deflated in 11.45 seconds using the front port. Thirty seconds into the cycle the rear port inflated in 2.02 seconds to 40 mmHg and released in 11.55 seconds.

In a similar fashion the Healthcare Service and Supply garment reached 40 mmHg pressure in 2.10 seconds using the top port and deflated in 12.46 seconds. Thirty seconds into the cycle the bottom port inflated the garment to 40 mmHg in 1.89 seconds and deflated in 12.61 seconds.

Conclusion Test #1

Based on the specification for the Vaso Press DVT Foot Garment, for which substantial equivalency is claimed, there is no significant difference in the inflation, deflation and pressure hold time.

Test #2- A Vaso Press DVT pump was used to inflate the Vaso Press Foot Garment to 120 mmHg. The timing motor was made inoperable so the pump delivered a continuous pressure of 120 mmHg to the garment for a period of six days. The garment was wrapped around a 5" PVC tube to simulate a foot.

Conclusion Test #2

At the end of the test period, the sample continued to function in the original and intended manner. This indicates that there were no leaks or failures because of this test

Signed: _____
Name: J. James Britton
Position: President
Date: November 30, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2001

Mr. J. James Britton
President
Britt Corporation
P.O. Box 547
Freehold, NJ 07728

Re: K003828/S1
Trade/Device Name: Vaso Press DVT Foot Garment #VP 520
Regulation Number: 870.5800 Compressible Limb Sleeve
Regulatory Class: II
Product Code: JOW
Dated: May 11, 2001
Received: May 12, 2001

Dear Mr. Britton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Sincerely yours,

510(k) Number (if known): K003828

Device Name: Vaso Press DVT Foot Garment

Indications for Use:

The Vaso Press DVT Foot Garment is recommended for use in patients for whom external compression therapy is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003828

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFT 801.109)